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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,330	02/13/2007	Colin Dickens	033335 R 050	2084

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EXAMINER	
OSINSKI, BRADLEY JAMES	

ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
05/07/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,330	DICKENS ET AL.	
	Examiner	Art Unit	
	BRADLEY J. OSINSKI	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2-20-2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-27 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Djupesland (2004/0112378) in view of Mishelevich et al (5,363,842).

a. Regarding claims 1 and 27, Djupesland discloses a nasal device in paragraph 211 to release an aerosol to the nasal turbinates past the nasal valve. In paragraph 210 a substantially gas-tight seal is disclosed. Paragraph 204 discloses an aerosol containing medicament. However, while Djupesland substantially discloses the method as claimed, it does not disclose preventing further gas flow for a time period to allow the particles to settle on the tissue. Mishelvevich et al discloses an aerosol inhaler in which the patient holds his or her breath for 10 seconds to allow smaller particles to settle. (Col.2 lines 20-29). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have a patient utilizing the device of Djupesland hold his/her breathe for 10 seconds to allow smaller particles to settle.

b. Regarding claim 2, Djupesland discloses aerodynamic diameters of about 8 microns being deposited in the nasal passageway (Paragraph 2)

c. Regarding claims 3, 22-26 and 30, While Djupesland substantially discloses the method as claimed such as delivering medication to the turbinate region, it does not disclose delivery volumes. Mishelevich et al discloses low inhalation rates below one liter per second to minimize loss of medicine through impact with various tissues, but does not disclose a delivery time. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to determine the volume of the turbinate region and nasal vestibule and deliver an appropriate amount, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233 (CCPA 1955).*

d. Regarding claim 4, See paragraphs 210 and 211 of Djupesland which disclose sealing the nostril.

e. Regarding claims 5-9, see claim 1 above, Mishelevich et al teaches holding ones breathe up to 10 seconds. (Col.2 lines 28-29)

f. Regarding claims 10-15, See claims 1 and 2 above, Mishelevich teaches holding ones breathe up to 10 seconds and Djupesland discloses an 8 micron diameter.

g. Regarding claims 16-21, Djupesland discloses the claimed invention except for the mass percent of active material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to vary the weight percentages of the various particles in the gas, since it has been held that

where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233 (CCPA 1955).*

2. Claims 28 and 29 rejected under 35 U.S.C. 103(a) as being unpatentable over Djupesland (2004/0112378) in view of Ruskewicz (5,971,951) and Mishelevich et al (5,363,842).

h. Regarding claims 28 and 29, while Djupesland substantially discloses the apparatus as claimed (see claims 1 and 2 above), it does not disclose means for indicating when a predetermined time period has elapsed after actuation of the delivery means or means for determining when a volume of gas has passed through the nozzle. However, Ruskewicz discloses a microprocessor for aerosol devices that discloses both audible and visual displays. The audible display activates if the patient has not delivered the full amount of medication (Col. 36 lines 50-52) and a visual display after a predetermined dose has been delivered (Col. 36 lines 47-49). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include audio and visual alerts as taught by Ruckewicz to the device of Djupesland to warn a patient when to take his or her medications and when the medication has been fully administered.

Response to Arguments

3. Applicant's arguments filed 2-20-2009 have been fully considered but they are not persuasive.

i. Applicant argues that one of ordinary skill in the art would not have found Mishelevich applicable to the nasal region. This is not persuasive because the reference is drawn to settling in the air tract. One of ordinary skill in the art would have recognized that different parts of the airway may be targeted by adjusting the inhalation method. A higher than one liter per second inhalation would result in medication impacting the throat and upper airways. It is the Examiner's position that one of ordinary skill in the art would have recognized that a breath hold results in settling of inhaled particles. One of ordinary skill in the art when dealing with medication being delivered via the patient's airways would be aware of the difficulties in designing both nasal and lower airway delivery systems to prevent loss to regions that are not intended to be targeted.

j. Applicant argues that the references applied to claims 28 and 29 do not teach means for indicating when a predetermined time period has lapsed after actuation of the delivery means, so as to allow the particles to settle on tissue. Examiner does not find this convincing. While the device does indeed count the number of doses administered, it also monitors each dosing event (Col.36 lines 50-54), indicating means for indicating when certain time periods have elapsed. Further evidence offered is Col.35 lines 51-54 which monitors how much of a drug has been delivered within a time period. This is tied with a warning/overdose system (Col.36 lines 2-4).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRADLEY J. OSINSKI whose telephone number is (571)270-3640. The examiner can normally be reached on M-Th 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley J Osinski/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767